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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: (510) 337-6821
FAX: (510) 337-6707

VIA FEDERAL EXPRESS

January 14, 1999

CFN: 2954164

Ms. Mei Chan, President
W&Y International
15015 Wicks Blvd.
San Leandro, CA 94577

WARNING LETTER

Re: Entry No. 620-0113680-3
Mis-invoiced food and drug products

Dear Ms. Chan,

On October 27, 1998, FDA's inspection of a shipment of bean thread offered for import into the United States by your firm under entry number 620-0113680-3 revealed mis-invoiced products. The mis-invoiced products included foods, drugs (pill, ointments, etc.), and clothing. Subsequent examination and analysis of the FDA regulated products showed the following violations:

Entry Number*	Product	Violation
1) I99-0113680-6/1/1	[redacted] cartons of Salted Mackerel	Decomposition
2) I99-0113680-6/1/2	[redacted] cartons of Salted Mackerel	Decomposition
3) I99-0113680-6/1/3	[redacted] cartons of unlabeled Dried Fish	Decomposition
4) I99-0113680-6/1/4	[redacted] cartons of Salted Olives	Insufficient Labeling
5) I99-0113680-6/1/5	[redacted] cartons of Dried Olives	Contaminated with insects; incorrect identity
6) I99-0113680-6/1/6	[redacted] cartons of Dried Lemon Peel	Inadequate labeling
7) I99-0113680-6/1/7	[redacted] boxes of tablets	Unapproved drug; No English label
8) I99-0113680-6/1/8	[redacted] boxes of ointment	Unapproved drug; No English label
9) I99-0113680-6/1/9	[redacted] cartons of tablets	Unapproved drug; No English label

10)I99-0113680-6/1/10	[redacted] cartons of pills	Unapproved drug; No English label
11)I99-0113680-6/1/11	[redacted] cartons of pills	Unapproved drug; No English label
12)I99-0113680-6/1/12	[redacted] cartons of tablets	Unapproved drug; No English label
13)I99-0113680-6/1/13	[redacted] cartons of capsules	Unapproved drug; No English label

*Because the products were mis-invoiced, FDA assigned entry number I99-0113680-6 to the products.

All of the above items were refused entry into the United States on December 24, 1998. Such mis-representation at the time of entry appears to be an attempt to circumvent FDA examination. Such mis-representation is a violation of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.) and may violate other provisions of law, such as 19 U.S.C. 1592, 18 U.S.C. 542 and 545.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice, such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported product meets all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Your written reply should be addressed to Food and Drug Administration, attention: Michael D. Wong, Acting Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro
District Director

cc: W. J. Byrnes & Co.
P.O. Box 280205
San Francisco, CA 94128